

REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the remarks herewith.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1-11 are pending. Applicants expressly state that the claims are intended to include and encompass the full scope of any equivalents. Thus, Applicants hereby expressly rebut any presumption that Applicants have narrowed or surrendered any equivalents under the doctrine of equivalents by presenting any remarks in this paper, and in no way do Applicants disclaim any of the territory with respect to any equivalent subject matter.

No fee is believed to be required in connection with the filing of this paper. If, however, any fee is deemed necessary, authorization is given to charge the amount of any such fee to Deposit Account No. 08-2525.

II. 35 U.S.C. §112, SECOND PARAGRAPH, REJECTION

Claims 2 and 6 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The Examiner believes that claims 2 and 6 refer to an "immune system disorder" comprising HIV infection. But Applicants respectfully point out that no such language exists in either claim 2 or 6. The Examiner is, therefore, asked to either clarify the rejection or, if the rejection is in error, withdraw it.

III. 35 U.S.C. §103 REJECTION

Claims 1-5 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over US 2003/0104581 to Hoess et al. in view of WO 95/03405 to Wagner et al. Applicants disagree.

Instant claim 1 provides for a process for the recombinant production of an antifusogenic peptide by expression of a nucleic acid encoding the antifusogenic peptide as a repeat peptide in a microbial host cell to form inclusion bodies which comprise said repeat peptide. The process comprises the steps of washing the inclusion bodies with a denaturing agent at a pH value of at

or below pH 6.5, solubilizing the washed inclusion bodies at a pH value of at least pH 9, and cleaving said repeat peptide to obtain said antifusogenic peptide.

The Examiner is respectfully reminded that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the teachings in the cited documents. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (B.P.A.I. 1993). For a Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Further, "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification."

Neither Hoess nor Wagner, either alone or in combination, teach, suggest or motivate a skilled artisan to practice Applicants' invention. Hoess report the production of antifusogenic with help from a fusion peptide, which is not an antifusogenic peptide. The Examiner's attention is directed to paragraph [0076] and [0069] wherein Hoess reports fusion polypeptides having an antifusogenic peptide and a non-antifusogenic peptide. This is not Applicants' invention, nor can Applicants' invention be extrapolated therefrom.

Wagner does not remedy the inherent deficiencies in Hoess. Wagner reports a method for the production of a modified core polypeptide obtained by a transpeptidase reaction. By contrast, Applicants invention presents a process wherein an antifusogenic peptide is produced as a repeat peptide of multiple copies of the desired antifusogenic peptide. This repeat peptide is obtained in an insoluble inclusion body. Applicants' process, therefore, advantageously eliminates the need of additional modification and purification steps present in the documents cited by the Examiner.

Even assuming, *arguendo*, that one skilled in the art would combine these three documents, any combination thereof would amount to, at most, an "obvious to try" scenario. The Federal Circuit, however, is clear that "obvious to try" cannot be the basis for rendering an invention unpatentable. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And as "obvious


to try" would be the only standard that would lend the Section 103 rejection any viability, the rejection must fail as a matter of law.

Consequently, reconsideration and withdrawal of the Section 103 rejection are respectfully requested.

CONCLUSION

In view of the remarks herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,



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